

CLAIMS

1. A method of treating a patient undergoing analgesic therapy, comprising the separate, simultaneous or sequential administration of a therapeutically effective amount of an analgesic and an analgesic sparing amount of devazepide.
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2. A method of treatment of a patient requiring analgesia, comprising the administration of a therapeutically effective amount of an analgesic whilst minimising the amount of said analgesic by the separate, simultaneous or sequential administration of a therapeutically effective amount of devazepide.
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3. The method according to claim 1, wherein the administration of a therapeutically effective amount of an analgesic is given with a superpotentiating amount of devazepide.
- 15 4. The method according to claim 1, wherein the amount of analgesic required by a patient is reduced by an amount of from 25% to 95% by weight of the amount of analgesic required in the absence of devazepide.
- 20 5. The method according to claim 4, wherein the amount of analgesic required by a patient is reduced by an amount of from 25% to 75% by weight of the amount of analgesic required in the absence of devazepide.
6. The method according to claim 1, wherein the opioid is selected from those which need to be administered at relatively high or increasing doses.
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7. The method according to claim 1, wherein the analgesic is an opioid.
8. The method according to claim 1, wherein the analgesic is selected from the group consisting of morphine, a salt thereof including the sulphate, chloride or hydrochloride; analgesics including meperidine, pentazocine, dextropropoxyphene, pethidine, fentanyl, alfentanil, alphaprodine, dextromoramide, diphenoxylate, dipipanone,
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meptazinol, methadone, nalbuphine, phenadoxone, phenazocine, remifentanyl, tramadol; the 1,4-hydromorphan opioid analgesics including butorphanol, morphine-6-glucuronide, codeine, dihydrocodeine, diamorphine, buprenorphine, heroin (diacetylmorphine), hydrocodone (dihydrocodeinone), hydromorphone (dihydromorphinone), levorphanol, metopon (methyldihydromorphinone), oxycodone (dihydrohydroxycodone), oxymorphone (dihydrohydroxymorphinone); and a salt of any of the aforementioned.

9. The method according to claim 8, wherein the opioid is naloxone.

10. The method according to claim 8, wherein the analgesic is selected from the group hydromorphone, oxycodone, morphine, and fentanyl or a salt thereof.

11. The method according to claim 10, wherein the opioid is fentanyl or a salt thereof.

12. The method according to claim 11, wherein the analgesic is morphine or morphine sulphate.

13. The method according to claim 7, wherein the ratio of devazepide to opioid is from 2:1 to 1:400 w/w.

14. The method according to claim 13, wherein the ratio of devazepide to opioid is from 2:1 to 1:200 w/w.

15. The method according to claim 14, wherein the ratio of devazepide to opioid is from 1:2 to 1:40 w/w.

16. The method according to claim 1, wherein the devazepide and/or the opioid is administered intravenously, intra-arterially, orally, intrathecally, intranasally, intrarectally, intramuscularly/subcutaneously, by inhalation or by transdermal patch.

17. The method according to claim 16, wherein the devazepide and/or the opioid is administered intravenously.

5 18. The method according to claim 17, wherein the intravenous administration is by intravenous bolus or a continuous intravenous infusion.

19. The method according to claim 16, wherein the devazepide and/or the opioid is administered subcutaneously.

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20. The method according to claim 19, wherein the subcutaneous administration is as a subcutaneous infusion.

15 21. The method according to claim 17, wherein the opioid and/or devazepide are administered intravenously or orally.

22. The method according to claim 21, wherein the opioid and/or devazepide are administered orally.

20 23. The method according to claim 17, wherein the opioid and the devazepide will be administered using the same mode of administration.

24. The method according to claim 17, wherein the opioid is administered orally and the devazepide is administered orally.

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25. The method according to claim 16, wherein the opioid is administered by transdermal patch.

30 26. The method according to claim 25, wherein the opioid is fentanyl, or a salt thereof.

27. The method according to claim 1, wherein the daily dosage of devazepide is up to 0.7 mg/kg/day.

28. The method according to claim 27, wherein the daily dosage of devazepide is
5 from 25 µg/kg/day to 0.7 mg/kg/day.

29. The method according to claim 28, wherein the daily dosage of devazepide is from 50 µg/kg/day to 0.5 mg/kg/day.

10 30. The method according to claim 28, wherein the dosage of devazepide is an oral dosage.

31. The method according to claim 30, wherein the devazepide is administered orally and the daily dosage of devazepide is from 0.07 mg/kg/day to 0.29 mg/kg/day.

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32. The method according to claim 27, wherein the devazepide is administered intravenously at a dosage of from 50 µg/kg/day to 0.5 mg/kg/day.

33. The method according to claim 7, wherein the dosage of the opioid is from 5 to
20 2000 mg daily.

34. The method according to claim 33, wherein the dosage of the opioid is from 10 to 240 mg daily.

25 35. The method according to claim 34, wherein the dosage of the opioid is from 5 to 100 mg daily.

36. The method according to claim 1, wherein the devazepide is provided as a composition incorporating a filler or other excipient.

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37. The method according to claim 36, wherein the composition is filled into a capsule.

38. The method according to claim 37, wherein the capsule is a gelatin capsule.

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39. The method according to claim 37, wherein the capsule has a fill weight of 150 mg \pm 5% by weight or 300 mg \pm 5% by weight.

40. The method according to claim 37, wherein the capsule formulation comprises
10 1.25 mg devazepide or 2.5 mg devazepide.

41. The method according to claim 40, wherein the 1.25 mg or 2.5 mg of devazepide is delivered at least twice daily.

15 42. The method according to claim 1, wherein the devazepide is substantially the S enantiomer.

43. The method according to claim 42, wherein the level of R enantiomer, which may be present as an impurity, is not greater than 1.5% w/w.

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44. The method according to claim 2, wherein the amount of analgesic required by the patient is reduced by an amount of from 25% to 75% by weight of the amount of analgesic required in the absence of devazepide.

25 45. The method according to claim 44, wherein the analgesic is an opioid.

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